IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL No. 2327**
THIS DOCUMENT RELATES TO: **WAVE 5 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE THE WAVE 5 TESTIMONY OF DR. SCOTT A. GUELCHER, PH.D.

Plaintiffs submit this Memorandum of Law in opposition to the "Motion to Exclude the Opinions and Testimony of Scott Guelcher, Ph.D." filed by Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon or Defendants").[1]

As this Court is well-aware by this point, Dr. Scott Guelcher, Ph.D., is a biomaterials expert identified by Plaintiffs for purposes of providing general opinions about the defective design of the Ethicon pelvic mesh products at issues in these cases. His opinions—and trial testimony—have been repeatedly vetted by this Court and others, and have been consistent throughout this litigation.[2] Dr. Guelcher's general causation opinions have consistently been based upon his decades of experience in biomaterials, the principles of biomaterials science, his

[1] Dkt. No. 4573 (Motion) and Dkt. 4574 (Memorandum) (Hereinafter referred to as "Ethicon's Brief").

[2] *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 709-710 (S.D. W. Va. 2014) (Dr. Guelcher Daubert Ruling in *Huskey Case*); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 737 (S.D. W. Va. 2014) (Dr. Guelcher August 25, 2014 Trial Testimony); *See* Mem. Op. and Order (*Daubert* Motion re: Scott Guelcher, Ph.D.), No. 2:12-cv-00738, at 5-8 (S.D. W. Va. Aug. 31, 2016) [Dkt. 124], attached as Ex. A.

review peer-reviewed publications, and his review of the Prolene oxidation studies that Ethicon performed internally.[3]

Ethicon devotes much of its Brief to challenging a 2017 peer-reviewed publication which Dr. Guelcher co-authored.[4] Ethicon's *Daubert* challenges toward this publication are without merit and are nothing more than Ethicon's own experts' disagreement with the conclusions in the study. The remainder of Ethicon's challenges to Dr. Guelcher's opinions are nothing more than a regurgitation of prior arguments that were covered—and rejected—in this Court's prior rulings. Those arguments need not be revisited here.

To be clear, while the 2017 peer-reviewed study provides *additional* support for Dr. Guelcher's opinions, the opinions themselves have not changed—and are as well-supported and scientifically reliable now as they have been throughout this litigation. For this reason, Ethicon's assertion that this study is central to Dr. Guelcher's opinions is simply wrong. It is merely one additional piece of peer-reviewed literature that supports his existing opinions. This Court has already acknowledged that Dr. Guelcher's opinions are sufficiently and independently supported by the relevant scientific literature. This newly published article is not the ultimate basis for his opinions. Moreover, the 2017 *Talley et al.* article at issue is the result of reliable science and the Court should ultimately have no question about its reliability. The study and resulting article is peer-reviewed and was accepted for publication in a well-respected scientific journal.[5] It is no less scientifically reliable than any of the countless other pieces of scientific literature relied upon by any of the experts—retained by Plaintiffs or Defendants—in this litigation. And similar

[3] *See* Ex. B, Guelcher Wave 5 Report and Ex. C, Guelcher Reliance Materials.
[4] Talley, et al., "Oxidation and Degradation of Polypropylene Transvaginal Mesh." J. Biomater. Sci., Polymer Ed. (2017)). Attached as Exhibit D.
[5] *See* Ex. D, A.D. Talley, B.R. Rogers, V. Iakovlev, R.F. Dunn, and S.A. Guelcher, "Oxidation and Degradation of Polypropylene Transvaginal Mesh." J. of Biomaterials Sci., Polymer Ed. (2017).

to the Court's treatment of other experts' reliance on the peer-reviewed literature, where a party disagrees with the conclusions of the scientific literature—or the experts' interpretation of it—that is merely fodder for cross examination and/or rebuttal opinions from the party's own experts. A party's disagreement with peer-reviewed, published literature does not require its exclusion. And it does not prevent an expert from discussing the peer-reviewed findings in front of the jury. Ethicon's challenges to Dr. Guelcher's opinions, and his reliance on the 2017 study, should be denied.[6]

ARGUMENT

I. The 2017 *Talley et al.* article is one additional piece of scientific literature which supports, but does not change, Dr. Guelcher's existing opinions.

As this Court has already acknowledged, Dr. Guelcher's opinions are sufficiently and independently supported by relevant scientific literature.[7] In Dr. Guelcher's Wave 5 report, he has cited a new and additional piece of relevant published peer-reviewed scientific literature—the 2017 *Talley et al.* study that he co-authored.[8] This additional publication does not change Dr. Guelcher's opinions from prior waves. Rather, this additional publication he cites merely supports his already-existing opinions.

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[6] For the sake of brevity and because the Court is fully aware of the legal standards governing the admissibility of expert testimony in the Fourth Circuit, Plaintiffs will not set forth a detailed discussion of the legal standard. Plaintiffs incorporate by reference the standard of review for *Daubert* motion as articulated by the Court in this litigation. *See* Ex. A, Mem. Op. and Order (*Daubert* Motion re: Scott Guelcher, Ph.D.), No. 2:12-cv-00738, at 4-5(S.D. W. Va. Aug. 31, 2016) [Dkt. 124].

[7] *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 709-710 (S.D. W. Va. 2014) (Dr. Guelcher Daubert Ruling in *Huskey Case*); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 737 (S.D. W. Va. 2014) (Dr. Guelcher August 25, 2014 Trial Testimony); *See* Ex. A, Mem. Op. and Order (*Daubert* Motion re: Scott Guelcher, Ph.D.), No. 2:12-cv-00738, at 5-7(S.D. W. Va. Aug. 31, 2016) [Dkt. 124].

[8] *See* Ex. B, Dr. Guelcher Wave 5 Report; Ex. D, A.D. Talley, B.R. Rogers, V. Iakovlev, R.F. Dunn, and S.A. Guelcher, Oxidation and Degradation of Polypropylene Transvaginal Mesh, J. of Biomaterials Sci., Polymer Ed. (2017).

Ethicon tries to point out "flaws" in the methodology of the *Talley et al.* article through critiques offered by its own experts, Dr. Thames and Dr. Maclean.[9] More specifically, Ethicon's expert, Dr. Maclean devotes pages 42-53 of his Wave 5 Report to offering his expert opinions about his perceived "flaws" of the *Talley et al.* study.[10] Each and every one of the alleged "flaws" in the *Talley et al.* article asserted in Ethicon's Brief is essentially a cut-and-paste of the Wave 5 Expert Report of Ethicon's own expert—Dr. Maclean.[11] Likewise, another one of Ethicon's experts, Dr. Thames, devotes pages 69-78 of his Wave 5 Report to offering his expert opinion about his perceived "flaws" in the *Talley et al.* study.[12] Ethicon's Brief also recites these same expert opinions from Dr. Thames as an attempt to challenge the credibility of the *Talley et al.* study.[13] In short, Ethicon's challenges to the *Talley et al*. article are nothing more than the rebuttal opinions of its own expert witnesses.

Under the principles of Rule 702 and *Daubert*, conflicting expert testimony alone cannot support a finding that the *Talley et al*. article is unreliable science, because it is not the Court's job to determine which expert is correct; but instead to act as a gate-keeper preventing unreliable and unsupported opinions from being heard by a jury.[14] Ethicon's rote recitation of its own experts' rebuttal opinions is not an appropriate way to challenge solid and reliable peer-reviewed science. And this disagreement between Ethicon's experts and Plaintiff's own expert is properly resolved at trial by the jury.

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[9] *See* Ex. E, Dr. Maclean Wave 5 Report at 42-53.
[10] *See* Ex. E , Dr. Maclean Wave 5 Report at 45-53.
[11] *See* Ex E, Dr. Maclean Wave 5 Expert Report at 45-53; *see also* Ethicon's Brief at 2-15.
[12] *See* Ex. F, Dr. Thames Wave 5 Report at 69-78.
[13] Ethicon's Brief at 2-15.
[14] *See In re: DePuy Orthopedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*, NO. 3:11-MD-2244-K 2014 U.S. Dist. LEXIS 97798, at *45 (N.D. Tex. July 18, 2014); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

The *Talley et al*. article was accepted for publication in the highly-regarded peer-reviewed Journal of Biomaterials Science, Polymer Edition, on January 3, 2017, and was subsequently published.[15] The article tests the hypothesis that polypropylene undergoes oxidation under *in vitro* conditions, resulting in degradation, by using accepted standard laboratory testing (Fourier Transform Infrared Spectroscopy (FTIR) and scanning electron microscopy (SEM)) to objectively assess any oxidation and degradation of mesh fibers.[16] The fact that the *Talley et al.* article has been subjected to the scrutiny of peer-review by other leading scientists in the field of biomaterials science certainly adds a layer of reliability to this article. The peer-reviewers serve as gate-keepers who thoroughly scrutinize the testing and methods before allowing for publication of the article. As Ethicon correctly points out, a peer-reviewed scientific article is not automatically deemed reliable merely because the article has gone through the peer-review process.[17] The *Daubert* court noted that while publication does not "necessarily" correlate with reliability, nevertheless "submission to the scrutiny of the scientific community is a component of 'good science,'" so that the fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, though not dispositive, consideration.[18] Plaintiffs

[15] *See* Ex. D, A.D. Talley, B.R. Rogers, V. Iakovlev, R.F. Dunn, and S.A. Guelcher, "Oxidation and Degradation of Polypropylene Transvaginal Mesh." J. of Biomaterials Sci., Polymer Ed. (2017).
[16] *Id*.
[17] *See* Ethicon's Brief at 2, FN 1.
[18] *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593-94 (1993). The cases cited by Ethicon for the proposition that "courts have excluded peer-reviewed literature" are inapplicable here. In *In re Viagra Prods. Liab. Litig.*, 658 F. Supp. 2d 936, 941-943 (D. Minn. 2009) the plaintiffs' expert's publication was found unreliable based on "acknowledged inaccuracies" that were so severe that they required the expert to supplement his expert report. In *Cedillo v. Sec'y of Health and Human Servs.*, No. 98-916V 2009 U.S. Claims LEXIS 146, at *376-385 (Fed. Cl. Feb. 12, 2009) the expert was the author of a widely-criticized article in which he found that the measles-mumps-rubella vaccine was associated with autism. The *Cedillo* court found the article unreliable because it had failed to gain acceptance in the medical community and was widely-criticized. *Id.* In the silicone breast implant litigation cited by

recognize that in certain limited circumstances, a peer-reviewed publication has been called into question or criticized and that being a peer-reviewed publication does not make an article *per se* reliable. However, for every one instance where Ethicon can point to a peer-reviewed article being scrutinized by a court, there are likely hundreds of instances where the same peer-reviewed process has provided the foundation for scientific reliability. And importantly, here, Ethicon has given the Court no legitimate reason to question the reliability of the *Talley et al*. article. That Ethicon and its own experts may disagree with the study is properly left for cross-examination.

Ethicon's assertion that the *Talley et al*. study is merely a repackaging of Dr. Dunn's previously-excluded testing from the *Mathison v. Boston Sci. Corp*., No. 2:13-cv-05851 2015 U.S. Dist. Lexis 59047 (S.D. W. Va. May 6, 2015) case does not convincingly call into question the *Talley et al.* article.[19] In *Mathison*, this Court did find that that Dr. Dunn's testing in that case "lacked sufficient indicia of reliability."[20] But at that point—over two years ago—Dr. Dunn's testing was at a very different stage of the scientific process. In contrast, the testing underlying the *Talley et al*. article has greater indicia of reliability—the testing in *Talley et al.* has gone through the scrutiny of objective review by other leading biomaterials scientists; and as such, is more reliable than Dr. Dunn's testing in *Mathison*. Moreover, as Dr. Guelcher also explained at his August 17, 2017 Wave 5 Deposition, the authors of the *Talley et al.* article performed additional analysis on the prior testing in order to improve the work to a standard where it could be sufficiently reliable to be accepted for publication.[21] Pages 3-5 of the *Talley et*

Ethicon, a panel of experts didn't reject specific studies, but rather addressed whether the body of research sufficiently established causation between silicone breast implants and various symptoms. *In re Silicone Gel Breast Implant Prod. Liab. Litig.*, (MDL 926), 1996 WL 34401766 (N.D. Ala. Oct. 31, 1996).

[19] *See* Ethicon's Brief at 3-5.

[20] *Mathison* 2015 U.S. Dist. LEXIS at *68.

[21] Ex. G, Dr. Guelcher Wave 5 Deposition Transcript, August 17, 2017 at 71:22-72:12.

al. study contain an extensive recounting of the materials, methods, and procedures that were followed in conducting the testing.[22] Additionally, the supplemental data for the *Talley et al*. article produced by Dr. Guelcher in advance of his deposition contains additional materials and methods that were utilized in the *Talley et al.* study.[23] Simply put, the *Talley et al.* study is a peer-reviewed publication which has undergone additional layers of analysis and recounts detailed materials, methods, and procedures—all of which provide significant additional indicia of reliability above the unpublished testing which was done by Dr. Dunn in the *Mathison* case. Ethicon's position that Dr. Guelcher should be precluded from referencing the *Talley et al*. study in the Wave 5 cases is without merit and its Motion should be denied.

II. Ethicon's insistence that Prolene is special has been previously rejected by this Court.

Like it did in *Huskey*, Ethicon once again takes the position that "Prolene's composition renders it distinct from other forms of polypropylene."[24] Ethicon simply retreads old ground by arguing that Dr. Guelcher relies on studies that: (1) do not assess Prolene; (2) cannot confirm that oxidizes inside the body; and (3) do not test or assess the ability of Prolene's antioxidants to slow the degradation of process.[25] This Court has repeatedly rejected this argument as being "wholly conceived by lawyers, [and] unfounded in science."[26] Nothing new is being argued here and the Court's ruling here should be no different.

III. Ethicon's argument regarding Dr. Guelcher's reliance on Ethicon documents is without merit.

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[22] *See* Ex. D, Talley, et al., "Oxidation and Degradation of Polypropylene Transvaginal Mesh." J. Biomater. Sci., Polymer Ed. (2017)).
[23] See Ex. H, Supplemental Data for *Talley et al*. study.
[24] Ethicon's Brief at 3 and 15-17.
[25] Ethicon's Brief at 15-17.
[26] *See e.g.*, *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703 (S.D. W. Va. 2014); Ex. A, Dr. Guelcher Wave 1 Order at 7.

Ethicon's argument that Dr. Guelcher cannot rely on Ethicon's internal studies on Prolene oxidation lacks merit and should be rejected as well.[27] These same Ethicon studies have been admitted at trial and have been discussed by several experts in this litigation for both Plaintiffs and Ethicon.[28] Ethicon's suggestion that these Prolene studies do not support Dr. Guelcher's opinions regarding Prolene degradation is, at best, nothing more than the description of a conflict in expert opinion, and "mere disagreement between experts is not, in itself, a reason to exclude an expert's testimony."[29] Dr. Guelcher clearly explains in his report that he has reviewed these Ethicon documents and explains the relevance they have to his opinions.[30] Experts for both Plaintiffs and Ethicon—including Dr. Guelcher and Dr. Thames—have previously testified at trial regarding these same documents and Ethicon has not explained why the result should be any different here.

IV. Dr. Guelcher's opinions regarding alternative designs are reliable.

Ethicon argues that non-mesh repair cannot constitute an alternative design.[31] First, Dr. Guelcher's general Wave 5 report is submitted in numerous cases, involving plaintiffs from numerous different states. It is beyond contention that the law regarding alternative designs varies from state-to-state. As such, Ethicon's arguments cannot be applied to all cases at issue—and therefore should not be decided on a general motion. Moreover, in making its argument, Ethicon cherry-picks rulings that have not been applied to the facts here, nor can they be applied to the entire Wave of cases before this Court. Indeed, in *Mullins*, a West Virginia-specific

[27] Ethicon's Brief at 17.
[28] *See e.g.*, *Huskey*, Tr. Ex. 13152 [Doc.411-2] (Eth.Mesh.07690752); *see* Ex. I, *Huskey* Tr. Aug. 25, 2014: 129:10-135:13 (Testimony of Dr. Guelcher); *see* Ex. I, *Huskey* Tr. Sept. 2, 2014: 36:16-48:20 (Testimony of Dr. Thames).
[29] Edwards v. Ethicon, Inc., 2014 U.S. Dist. LEXIS 92316, at *70 (S.D. W. Va. July 8, 2014).
[30] *See* Ex B, Dr. Guelcher Report at 14.
[31] Ethicon's Brief at 18.

determination, this Court wrote "[o]nce the court determines that the plaintiffs have provided sufficient evidence to identify a comparable product or design concept, whether the design features of the comparable product or the design concept existing at the time of the TVT's manufacturer is an alternative, feasible design for the TVT is a factual question left to the jury."[32] There is nothing in Ethicon's Brief that would preclude Dr. Guelcher from offering opinions that biologic repairs are safer alternatives to using polypropylene mesh. Ethicon's Motion should be denied.

Moreover, there is nothing in Ethicon's discussion of the recent Fourth Circuit decision (*Nease v. Ford Motor*) that changes how the Court analyzes the reliability of Dr. Guelcher's alternative design opinions.[33] Ethicon asserts that Dr. Guelcher has not actually tested any of the alternative procedures and materials he proposes.[34] "Testing," however, has long been a factor considered by courts when considering the reliability of an expert's opinion. But there is no *requirement*, in *Nease* or elsewhere, that an expert must perform testing on a product—it is just one of the factors taken into account. Indeed, as the Fourth Circuit reiterated in *Nease*, an expert may support his or her opinions through "evidence such as test data[35] *or relevant literature in the field*."[36]

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[32] *Mullins v. Johnson & Johnson*, NO. 2:12-cv-02952, 2017 U.S. Dist. LEXIS 25187, at *29 (S.D. W. Va. Feb 23, 2017).
[33] Ethicon's Brief at 19 (citing *Nease v. Ford Motor Co.*, 848 F.3d 219 (4th Cir. 2017). *Nease* was also decided under W. Va. law and cannot be applied to the entire Wave of cases before the Court.
[34] Ethicon's Brief at 19.
[35] In *Nease*, the court merely focused on plaintiff's expert's lack of testing of the purported defect because there was no other support provided. *Id.* at 231 ("Testing was of critical importance *in this case*….) (emphasis added).
[36] *Nease*, 848 F.3d at 231 (emphasis added).

Plaintiff's expert in *Nease* primarily relied upon a Ford FMEA that did not even apply to the model year of the car (2001 Ford Ranger) at issue.[37] Moreover, he acknowledged that: (1) during his examination of the plaintiff's car, he did not observe the conditions he opined could result in the malfunction; (2) the part at issue in plaintiff's car operated correctly during his examination of it; and (3) he had never—in plaintiffs' car or any other car—observed the defective condition he claimed could exist.[38] In fact, plaintiff's expert could not even distinguish a working part from a non-working part in videos shown to him during trial.[39]

Here, unlike in *Nease*, Dr. Guelcher relies upon his experience in biomaterials, Ethicon's internal studies on mesh and Prolene specifically, all of the clinical literature about the foreign body response to polypropylene sutures and mesh, the many clinical papers comparing the use of biologics and other suture repairs to that of polypropylene mesh and his own experience, training, and expertise in developing new products to be used inside the human body. His alternative design opinions are firmly grounded in the clinical and scientific literature. They are based on measurable data with repeatable results from countless scientific experiments, decades of clinical usage and scientific study, and many papers that are recounted in his report.[40]

V. Dr. Guelcher will not offer opinions on medical complications, in accordance with this Court's previous ruling on this issue.

This Court has previously ruled that Dr. Guelcher is not qualified to offer opinions on medical complications caused by polymer degradation.[41] Dr. Guelcher's Wave 5 trial testimony will certainly comply with this bounds of this Court's Order.

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[37] *Nease*, 848 F.3d at 224-25, 226, 232.
[38] *Id.* at 225-226, 231-32.
[39] *Id*. at 226.
[40] *See* Ex. C, Dr. Guelcher Reliance List.
[41] Ex. A, Mem. Op. and Order (*Daubert* Motion re: Scott Guelcher, Ph.D.), No. 2:12-cv-007382327, at 6 (S.D. W. Va. Aug. 31, 2016) [Dkt. 124].

VI. Dr. Guelcher will not testify regarding Ethicon's knowledge, state of mind, or corporate intent.

Counsel for Ethicon correctly points out that this Court has previously disallowed expert to testify regarding a corporation's knowledge or state of mind. Dr. Guelcher only intends to testify as to Ethicon corporate documents at trial for the purpose of explaining the basis for his opinions, in accordance with this Court's previous rulings on this issue.[42]

CONCLUSION

Ethicon's Brief does not state any compelling reason for excluding or limiting Dr. Guelcher's testimony beyond the bounds already set by this Court's prior rulings. Regarding the *Talley et al*. article, Plaintiffs respectfully ask that this Court either (1) deny Ethicon's request to preclude Dr. Guelcher from testifying about this article at trial; or (2) reserve ruling on whether Dr. Guelcher may reference the *Talley et al*. study at trial until the time of trial.[43] Ethicon's Motion should be denied.

Dated: September 14, 2017

Respectfully submitted,

/s/ Edward A. Wallace
Edward A. Wallace
Mark R. Miller
Timothy E. Jackson
Wexler Wallace LLP
55 W Monroe Street, Suite 3300
Chicago, Illinois 60603
T. (312) 346-2222

[42] *Huskey*, 29 F. Supp. 3d at 702-703.

[43] If at that time, Dr. Guelcher were instructed by the Court to avoid reference to the 2017 *Talley et al*. study at trial, he could certainly do so and his opinions would be unchanged from the opinions allowed by this Court in the *Huskey* case and in the priors Waves. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 709-710 (S.D. W. Va. 2014) (Dr. Guelcher Daubert Ruling in *Huskey Case*); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 737 (S.D. W. Va. 2014) (Dr. Guelcher August 25, 2014 Trial Testimony); *See* Ex. A, Mem. Op. and Order (*Daubert* Motion re: Scott Guelcher, Ph.D.), No. 2:12-cv-00738, at 5-6 (S.D. W. Va. Aug. 31, 2016) [Dkt. 124].

F. (312) 346-0022
E. eaw@wexlerwallace.com
mrm@wexlerwallace.com
tej@wexlerwallace.com

CERTIFICATE OF SERVICE

I hereby certify that on September 14, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ Edward A. Wallace